

Att'y Dkt. No. US-1280

U.S. App. No: 09/868,338

**REMARKS**

Claims 1-16 are pending; claims 5, 6, and 8 have been cancelled; claims 1-4, 9-14 have been withdrawn. Claim 7 has been amended and claims 15 and 16 are pending. No new matter is added by the foregoing amendments. Since the amendment of claim 7 further simplifies the issues for appeal and presents no new issues requiring a further search, applicants respectfully request entry. Favorable reconsideration, reexamination, and allowance of the present patent application are respectfully requested in view of the foregoing amendments and the following remarks.

***The Rejection under 35 U.S.C. §101 and §112, 1<sup>st</sup> Paragraph***

Claims 7, 15, and 16 were rejected under 35 U.S.C. §101, as allegedly not being supported by a specific and substantial asserted utility or a well-established utility. The Examiner has stated that applicants have failed to provide a "specific utility", a "substantial utility" or a "well established" utility. The Examiner also asserts there is no "real world" use for the claimed invention.

The Examiner has continued to assert that the asserted utility is for "treating an unspecified, undisclosed disease or condition" (see office action, page 6). Again, this is entirely false as applicants do not state anywhere or suggest, either explicitly or inherently, that this is the asserted utility. The asserted utility of the claimed gene and protein of the present invention is that they are useful for breeding of a microorganism for the purpose of modifying transport of amino acids across a cell membrane (see page 1, lines 9-12, page 3, lines 3-7, page 8, table 1, and page 21, lines 15-19). This has nothing to do with treating a disease or condition. If the Examiner has not understood the asserted utility, he certainly cannot meet his initial burden of providing evidence to establish reasonable doubt, and thereby shifting the burden to applicants. For this reason alone, the rejection should be

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withdrawn.

The Examiner has injected requirements and standards into 35 U.S.C. §101 that simply do not exist. Patent applicants are required to assert a utility in the specification for the claimed invention under §101, and that utility must be shown to be “operable to achieve useful results”. See *Swartz*. There is no requirement in the statute or as interpreted by the Courts that the utility be “specific”, “substantial”, or “well-established”. In fact, inoperable embodiments are permitted. *Atlas Powder co. v. E.I. du Pont De Nemours & Co.*, 750 F.2d 1569, 1576 (Fed. Cir. 1984). The Court has also read this requirement as meaning the utility must be ‘practical’ *In re Zeigler* 992 F.2d 1197 (Fed. Cir. 1993). The seminal case, *Brenner v. Manson* 383 U.S. 519 (1966), did state that to satisfy §101, the disclosure must assert a “specific benefit... in currently available form” and was cited by the Federal Circuit in reference to an asserted utility of a chemical compound as “a potential role as an object of use testing”. See *Zeigler*. However, there is no requirement for a “substantial” utility, nor a “well-established” utility.

The asserted utility of the claimed gene and protein of the present invention is that they are useful for breeding of a microorganism for the purpose of modifying transport of amino acids across a cell membrane (see page 1, lines 9-12, page 3, lines 3-7, page 8, table 1, and page 21, lines 15-19). This is applicant’s asserted utility for the claimed invention. To assert the objective truth of this statement, applicant has provided evidence that the claimed gene and protein are members of a family of genes/proteins which are known in the art to be useful as ATP-binding cassette transporters (ABC transporters). The ATP transporters have an established physiological function of uptake and excretion of substances into and out of the cell, hence the term ‘transporters’. Furthermore, applicants

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have provided useful information based upon the homology of the novel transporter to assert the utility. Until the Examiner can successfully raise reasonable doubt of this utility, the burden remains with the Examiner. Applicants have provided overwhelming evidence that the novel protein is a member of the ABC transporter family, and specifically for its use in exporting amino acids from a bacterial cell during fermentation. Applicants continue to assert that the Examiner has failed to establish reasonable doubt of the objective truth of any of the above statements.

The gene/protein of the present invention has several asserted utilities: the transport of amino acids across the membrane of the cell, for secreting amino acids out of the cell, and for importing amino acids into the cell. Transporters have a defined and credible usefulness which is practical in that these proteins can be expressed in a cell and effect the transport of substances, and in the instant invention, amino acids, inside and outside of the cell. Any person of ordinary skill in the art would recognize this utility as useful and 'in currently available form' and not merely an object of further 'use-testing'. The protein of the instant invention is clearly an ABC transporter, and this utility has been established by the inventors. No further use-testing needs to be conducted to establish utility. Although further research might be conducted to further evaluate the protein, the current evidence as presented is sufficient to satisfy §101, since it shows the claimed gene/protein's usefulness as a transporter in the cell machinery.

The Examiner has based the rejection on the assertion that the substance to be transported has not been identified, nor has the transporter been identified as a 'exporter' or 'importer'. To the contrary, there are multiple instances whereby applicants assert in their specification that the transporter is to the exporting of amino acids for use in bacterial

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fermentative production of said amino acids. See page 3, lines 3-7, page 7, lines 6-14, and table 1 on page 8. Applicants clearly state that the asserted utility of the novel ABC transporter gene/protein is for transporting amino acids in/out of the cell. Second, why must the asserted utility have a therapeutic use of the 'real world'? The applicants do not assert that the claimed invention is useful for treatment of diseases or conditions. In fact, as anyone of ordinary skill in the art would know, amino acid production using bacteria is a large billion dollar business in the United States and around the world. Bacterial breeding methods for increasing amino acid production are the research focus of many international corporations, including the assignee of the present application. Establishing new bacteria which can efficiently produce amino acids is also an area of intense research interest for many of these same companies. Amino acids have many 'real world' applications, only a few of which are to treat 'diseases or conditions'. In fact, one of the most common uses for amino acid is for feed supplements for livestock. The Examiner cannot require proof of pharmaceutical utility, particular where none has been asserted. Again, the Examiner has failed to establish reasonable doubt of applicant's asserted utility, which has nothing to do with treatment of any disease or condition.

The gene/protein of the present invention is useful, in one instance, as a transporter for amino acids to the outside of the cell membrane. The Examiner has failed to establish reasonable doubt that the claimed gene/protein is not useful as asserted by applicants. The gene/protein is clearly a member of the ABC transporter family of proteins. This family of proteins is clearly involved in the uptake and secretion of amino acids in bacterial cells. Finally, it is clear that production of an amino acid can be enhanced by disrupting a gene involved in uptake of amino acids or amplification of a gene involved in

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secretion of an amino acid. These utilities are involved in amino acid production, not diagnosing, preventing, and/or treating a disease, as the Examiner is asserting.

For this reason, applicants assert that the Examiner has failed to establish reasonable doubt as to the operability of the claimed invention, particularly since the Examiner does not appear to understand or comprehend the asserted utility. Therefore, the burden cannot shift to applicants. In the interest of advancing prosecution, however, applicants have provided evidence and arguments to rebut the Examiner's asserted lack of utility. For these reasons, applicants respectfully request the rejection be withdrawn.

***The Rejection under 35 U.S.C. §112, 1<sup>st</sup> Paragraph***

Claims 7, 15, and 16 are rejected under 35 U.S.C. §112, 1<sup>st</sup> paragraph for allegedly not being able to know how to use the claimed invention. Again, the Examiner asserts that the person of skill in the art would not know how to use the invention since no specific function has been disclosed for the claimed polynucleotide. As stated above, the claimed gene/protein has been identified as a member of the ABC transporter family, members of which are useful as transporters of amino acids outside of the cell (see evidence and arguments presented above). This is a 'real world' utility since amino acid production is a multi-billion dollar business.

Applicants have limited their claims so that only the DNA sequence of SEQ ID No. 7 is encompassed. The language allowing for DNA and/or protein variants has been cancelled. In light of the amendments and the arguments and evidence presented above, applicant's respectfully request that the rejection be withdrawn.

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***The Rejection under 35 U.S.C. §112, 1<sup>st</sup> Paragraph, written description***

Claims 7, 15, and 16 are rejected under 35 U.S.C. §112, 1<sup>st</sup> paragraph as allegedly containing subject matter which was not described in the specification in such as way as to reasonably convey to one skilled in the relevant art that the inventors had possession of the claimed invention. The claims as amended are directed to a DNA sequence which is the sequence shown in SEQ ID NO. 7, or a protein encoded by said DNA. For the reasons presented above, applicants respectfully request that the rejection be withdrawn.

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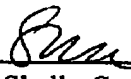
***Conclusion***

For at least the foregoing reasons, Applicant respectfully submits that the present patent application is in condition for allowance. An early indication of the allowability of the present patent application is therefore respectfully solicited.

If Examiner Basi believes that a telephone conference with the undersigned would expedite passage of the present patent application to issue, he is invited to call on the number below.

It is not believed that extensions of time are required, beyond those that may otherwise be provided for in accompanying documents. However, if additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. § 1.136(a), and the undersigned authorizes such fee therefor to be charged to our deposit account 50-3077.

Respectfully submitted,

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Date: January 4, 2005